



UNITED STATES PATENT AND TRADEMARK OFFICE

[Signature]
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/981,002

10/17/2001

Wayne M. Barnes

TKR 2050.1

6531

26263

7590

11/06/2006

SONNENSCHN NATH & ROSENTHAL LLP

P.O. BOX 061080

WACKER DRIVE STATION, SEARS TOWER

CHICAGO, IL 60606-1080

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,002

Applicant(s)

BARNES, WAYNE M.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-13 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6-13 and 17-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status

1. The current application has been suspended pending the outcome of Interference I-105,320. That interference has now concluded, with priority being awarded to the opposing party, Sorge. The current party, Barnes, filed for Adverse Judgment. Therefore, the applicant is estopped from asserting prior invention relative to Sorge (see MPEP 2308.03, for example). The current rejections all involve the Sorge patent. Since these rejections are not necessitated by an action by Applicant, the current action is NON-final.

Priority

2. The current application claims priority from 08/021,623, filed February 19, 1993. That application, now U.S. Patent 5,436,149, does not provide descriptive support for the current claims. There is no support in that application for Thermotoga maritima DNA polymerase or for Pyrococcus GB-D polymerase as listed in claim 3 of the current application. Therefore, the claims do not receive priority to the parent application and are given a priority date of the filing of the straight continuation parent, 08/931,818 of September 16, 1997.

Claim Objections

3. Claim 3 is objected to because of the following informalities: The word "martima" should be "maritima". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

5. Claims 3, 4, 6-13, 17-22, 24, 26, 27, 29, 30, 32, 34 and 35 are rejected under 35 U.S.C. 102(f) and (g) as being anticipated by Sorge et al (U.S. Patent 5,556,772).

Sorge teaches a kit for the synthesis of a polynucleotide, said kit comprising:

(a) a first DNA polymerase, wherein said first polymerase possesses 3'-5' exonuclease activity selected from the group consisting of Pyrococcus furiosus DNA polymerase, Thermotoga maritima DNA polymerase, Thermococcus litoralis DNA polymerase, and Pyrococcus GB-D DNA polymerase, and

(b) a second DNA polymerase, wherein said second polymerase lacks 3'-5' exonuclease activity selected from the group consisting of Thermus aquaticus DNA polymerase, (exo-) Thermococcus litoralis DNA polymerase, (exo-) Pyrococcus furiosus DNA polymerase, and (exo-) Pyrococcus GB-D DNA polymerase (see claim 1 of Sorge, which is literally identical to the current claim).

With regard to claim 4, Sorge teaches a kit according to claim 1, wherein said first and second DNA polymerases are thermostable (see claim 2 of Sorge).

With regard to claim 6, Sorge teaches a method of amplifying a polynucleotide sequence, said method comprising: the steps of mixing a composition, with a synthesis primer, and a synthesis template, said composition comprising (a) a first DNA polymerase, wherein said first polymerase possesses 3'-5' exonuclease activity selected from the group consisting of Pyrococcus furiosus DNA polymerase, Thermotoga maritima DNA polymerase, Thermococcus litoralis DNA polymerase, and Pyrococcus GB-D DNA polymerase, and (b) a second DNA polymerase, wherein said second polymerase lacks 3'-5' exonuclease activity selected from the group consisting of Thermus aquaticus DNA polymerase, (exo-) Thermococcus litoralis DNA polymerase, (exo-) Pyrococcus furiosus DNA polymerase, and (exo-) Pyrococcus GB-D DNA polymerase (see claim 3 of Sorge).

With regard to claim 7, Sorge teaches a method according to claim 3 wherein said first and second DNA polymerases are thermostable (see claim 4 of Sorge).

With regard to claim 8, Sorge teaches a method according to claim 3, wherein said first DNA polymerase is Pyrococcus furiosus DNA polymerase (see claim 5 of Sorge).

With regard to claim 9, Sorge teaches a method according to claim 4, wherein said second DNA polymerase is Thermus aquaticus DNA polymerase (see claim 6 of Sorge).

With regard to claim 10, Sorge teaches a method according to claim 5, wherein said second DNA polymerase is Thermus aquaticus DNA polymerase (see claim 7 of Sorge).

Art Unit: 1637

With regard to claim 11, Sorge teaches a kit according to claim 2, wherein said first DNA polymerase is *Pyrococcus furiosus* DNA polymerase (see claim 8 of Sorge).

With regard to claim 12, Sorge teaches a kit according to claim 2, wherein said second DNA polymerase is *Thermus aquaticus* DNA polymerase (see claim 9 of Sorge).

With regard to claim 13, Sorge teaches a kit according to claim 8, wherein said second DNA polymerase is *Thermus aquaticus* DNA polymerase (see claim 10 of Sorge).

With regard to claims 17, 19, 20, 29, Sorge teaches a first archaeobacterial DNA polymerase, Pfu polymerase (see claim 1).

With regard to claims 18, 21, 22, 24, 27, 30, 32, 35, Sorge teaches the use of Taq polymerase (see claim 1).

With regard to claims 26, 27, and 34, Sorge teaches the use of *Thermococcus litoralis* DNA polymerase and Taq polymerase (see claim 1, where Tli is the Vent DNA polymerase).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1637

7. Claims 23, 25, 28, 31, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorge et al (U.S. Patent 5,556,772) in view of Barnes et al (WO94/26766).

Sorge teaches a kit for the synthesis of a polynucleotide, said kit comprising:

(a) a first DNA polymerase, wherein said first polymerase possesses 3'-5' exonuclease activity selected from the group consisting of Pyrococcus furiosus DNA polymerase, Thermotoga maritima DNA polymerase, Thermococcus litoralis DNA polymerase, and Pyrococcus GB-D DNA polymerase, and

(b) a second DNA polymerase, wherein said second polymerase lacks 3'-5' exonuclease activity selected from the group consisting of Thermus aquaticus DNA polymerase, (exo-) Thermococcus litoralis DNA polymerase, (exo-) Pyrococcus furiosus DNA polymerase, and (exo-) Pyrococcus GB-D DNA polymerase (see claim 1 of Sorge, which is literally identical to the current claim).

With regard to claim 4, Sorge teaches a kit according to claim 1, wherein said first and second DNA polymerases are thermostable (see claim 2 of Sorge).

With regard to claim 6, Sorge teaches a method of amplifying a polynucleotide sequence, said method comprising: the steps of mixing a composition, with a synthesis primer, and a synthesis template, said composition comprising (a) a first DNA polymerase, wherein said first polymerase possesses 3'-5' exonuclease activity selected from the group consisting of Pyrococcus furiosus DNA polymerase, Thermotoga maritima DNA polymerase, Thermococcus litoralis DNA polymerase, and Pyrococcus GB-D DNA polymerase, and (b) a second DNA polymerase, wherein said

Art Unit: 1637

second polymerase lacks 3'-5' exonuclease activity selected from the group consisting of Thermus aquaticus DNA polymerase, (exo-) Thermococcus litoralis DNA polymerase, (exo-) Pyrococcus furiosus DNA polymerase, and (exo-) Pyrococcus GB-D DNA polymerase (see claim 3 of Sorge).

With regard to claim 7, Sorge teaches a method according to claim 3 wherein said first and second DNA polymerases are thermostable (see claim 4 of Sorge).

With regard to claim 8, Sorge teaches a method according to claim 3, wherein said first DNA polymerase is Pyrococcus furiosus DNA polymerase (see claim 5 of Sorge).

With regard to claim 9, Sorge teaches a method according to claim 4, wherein said second DNA polymerase is Thermus aquaticus DNA polymerase (see claim 6 of Sorge).

With regard to claim 10, Sorge teaches a method according to claim 5, wherein said second DNA polymerase is Thermus aquaticus DNA polymerase (see claim 7 of Sorge).

With regard to claim 11, Sorge teaches a kit according to claim 2, wherein said first DNA polymerase is Pyrococcus furiosus DNA polymerase (see claim 8 of Sorge).

With regard to claim 12, Sorge teaches a kit according to claim 2, wherein said second DNA polymerase is Thermus aquaticus DNA polymerase (see claim 9 of Sorge).

Art Unit: 1637

With regard to claim 13, Sorge teaches a kit according to claim 8, wherein said second DNA polymerase is *Thermus aquaticus* DNA polymerase (see claim 10 of Sorge).

With regard to claims 17, 19, 20, 29, Sorge teaches a first archaeobacterial DNA polymerase, Pfu polymerase (see claim 1).

With regard to claims 18, 21, 22, 24, 27, 30, 32, 35, Sorge teaches the use of Taq polymerase (see claim 1).

With regard to claims 26, 27, and 34, Sorge teaches the use of *Thermococcus litoralis* DNA polymerase and Taq polymerase (see claim 1, where Tli is the Vent DNA polymerase).

Sorge does not teach the use of Klentaq-278 as the second DNA polymerase.

Barnes teaches Klentaq-278 (see page 9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Klentaq-278 of Barnes in the amplification mixtures of Sorge since Barnes teaches that Klentaq-278 "exhibits thermostability at temperatures above those reported for any previous variant of *Thermus aquaticus* DNA polymerase and has demonstrated a fidelity in final PCR products which is greater than that of WT *Thermus aquaticus* DNA polymerase, when both are utilized at the 72.degree. C. temperatures recommended for DNA synthesis. (see page 9, lines 14-


18)." Thus, an ordinary practitioner would have chosen Klentaq-278 as the second, exo-, polymerase in the method of Sorge, in order to obtain the improved thermostability and fidelity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jeffrey Fredman
Primary Examiner
Art Unit 1637
